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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/766,113	01/19/2001	Wesley B. Bruce	1166	1157

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EXAMINER
HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 03/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/766,113	BRUCE ET AL.	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *11-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3, 4* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of Applicant's restriction election, Paper No. 8, filed 30 January 2003. Applicant elects Group I and SEQ ID NO: 2, claims 1-10, with traverse. Applicant traverses the Examiner's statement that the inventions of SEQ ID NO: 1-8 are different based on the use of these sequences as hybridization probes. Applicant says that these sequences are novel root preferred promoter elements, not hybridization probes. Applicant's traversal has been considered and is unpersuasive because one intended use does not preclude another intended use, and indeed these DNA sequences can be used in both ways. Applicant traverses, stating primarily that MPEP 803.04 says that up to 10 independent and distinct nucleotide sequences will be examined in a single application without restriction. Applicant's traversal has been considered and is unpersuasive because this MPEP language is directed mainly to EST sequences, because the resources in the PTO have changed and examination of more than one sequence is an undue burden, and because one sequence is considered "up to 10". Applicant traverses, stating primarily that examination of Groups I, II and III would not be an undue burden because the searches are similar. Applicant's traversal has been considered and is unpersuasive because even though the searches overlap, they are not coextensive. Accordingly, this restriction is made Final.

2. Claims 1-23 are pending. Claims 11-23 are nonelected. Claims 1-10 and SEQ ID NO: 2 are examined in the instant application. .

3. Claims 5 and 10 are objected to because the nonelected invention should be deleted from the claims.

Information Disclosure Statement

4. Initialed and dated copies of Applicant's IDS form 1449, Papers No. 3 and 4, dated 2 July 2001, and 18 December 2001 are attached to the instant Office action.

Specification

5. The specification is objected to because of the following: current US patent policy does not permit the use of hyperlinks in the specification. Such links are directed to an Internet site, the contents of which are subject to change without notice. Therefore, the potential for inclusion of new matter would be a constant problem. See page 12 for example. Correction is required.

Claim Rejections - 35 USC § 112 second

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1,

- (a) recites a "5' flanking sequence, a central random sequence, and a 3' flanking sequence" but does not give the order of these sequences with respect to one another.
- (b) recites a "preferred plant tissue" but does not what the preference is; recites "conditions promoting complex formation" but does not say what the the "complex" is; "said proteins" lacks antecedent basis.
- The process of going from step (b) to (c) is missing an essential step, that of forming complexes between the two components.
- In (c)"said formed complexes" lacks antecedent basis.
- In (d) "said separated complexes" lacks antecedent basis; furthermore, step (d) lacks essential steps of "producing isolated complexes", followed by a step of separating the oligonucleotides from the isolated complexes.
- Step (h), "assessing" unclear; assessing what?
- Step (i), "increased" is indefinite because it lacks comparative basis: "increased" with respect to what?
- A step is missing between (j) and (k), that of expressing the expression cassette.
- A step is missing between (k) and (l), that of choosing an oligonucleotide.

Claim 1 is incomplete because the desired product, a tissue-preferred plant promoter element, is not produced by final step of the claim.

In Claims 5 and 10,

- (b) is indefinite because it recites a sequence that hybridizes "under stringent conditions" but does not give specifics of those conditions—time, temperature, salt concentration, for example.
- (c) recites "maintain function" but no specific function has been recited.

In claim 6, "gene" is unclear because a "gene" implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Since this does not appear to be Applicant's intention, the language "a DNA of interest" is suggested. Or Applicant may recite the various components of the "gene" desired. All subsequent recitations of this language are also rejected.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 112-1 - Written Description

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a plant promoter comprising at least one tissue-preferred plant promoter element and related polynucleotides. However, the specification does not disclose what structural features need to would be present in the claimed sequences that would result in the claimed promoter activity. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

> See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention . . ."

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

Claim Rejections - 35 USC § 112-Enablement

9. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims to a nucleic acid of SEQ ID NO: 2, does

not reasonably provide enablement for any sequences comprising a plant promoter having at least one tissue-preferred plant promoter element, or for a root-preferred plant promoter element where the nucleotide sequence comprising at least 7 contiguous nucleotides of SEQ ID NO: 2 where the nucleotides maintain function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification sets forth a polynucleotide represented as SEQ ID NO: 1. However, the specification does not indicate what structural or functional properties of SEQ ID NO: 1 would represent a plant promoter having at least one tissue-preferred plant promoter element.

Sequence homology is not sufficient to predict function of encoded sequences. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and "overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar functions" (the last sentence of the first paragraph of page 248). Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph). In addition, Smith et al (Nature Biotechnology 15:1222-1223, November 1997) teach that "there are numerous cases in which proteins of very different functions are homologous" (page 1222, the first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133, April 1999) discusses the problem of inferring function from homology, stating that "most homologs must have different molecular and cellular functions" (see the second full

paragraph of the second column of page 132, for example). Furthermore, Borks (TIG 12, 10:425-427, October 1996) teaches numerous problems with the sequence databases that can result in the misinterpretation of sequence data.

Even if Applicant were enabled for plant promoter comprising a root-preferred plant promoter element comprising SEQ ID NO: 2, Applicant is not be enabled for all tissue-preferred plant promoter elements, or all plants, or for the broad scope of the claims. This is because using a promoter isolated from one species of plant would produce unpredictable results when said promoter is used to specify expression of a gene in another species of plant. Oommenn et al (1994, The Plant Cell 6:1789-1803) teach that the alfalfa isoflavone reductase promoter exhibits a different expression pattern in tobacco as compared to the expression in alfalfa. In tobacco, the alfalfa isoflavone reductase promoter expressed in vegetative tissues and in reproductive organs whereas the same construct only expressed in the root meristem, cortex and nodules of alfalfa plants (abstract).

Nor are fragments or "functional fragments" of a promoter predictable as to their expression characteristics. Benfry, et al, US 5, 110, 732, issued 5 May 1992, shows that various fragments of the CaMV 35S promoter exhibit different expression characteristics in tobacco tissue. That one fragment exhibits selective expression in root tissue and in the radical of the seed; whereas, another fragment exhibits constitutive expression in plant tissue other than root tissue

Whereas one of skill in the art can readily insert nucleic acids into plants, guidance is required as to what sequences under what conditions would result in a tissue-preferred plant promoter element. To require one skilled in the art to make changes by random experimentation without guidance as to how to eliminate inoperable embodiments, other than by trial and error is an invitation to experiment requiring excessive and undue experimentation. It would require undue experimentation to identify other polynucleotides which would have the desired activity since specific motifs and structural features are not described. In view of the breadth of the claims (any plant, any plant tissue, any tissue-preferred element, any root-preferred element, and any promoter), the unpredictably of the promoter art, the lack of guidance in the specification, undue trial and error experimentation would be required to enable the invention as commensurate in scope with the claims.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being obvious over Bruce, et al, US 6, 140,080, issued October 31, 2000.

12. The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The claimed promoter made by the method of providing a mix of oligonucleotides, contacting with nuclear proteins, isolating complexes and then the complexed oligonucleotide, amplifying the oligonucleotide by PCR, isolating

oligonucleotides re electrophoretic mobility, putting the oligonucleotide with a promoter and assaying expression (steps a-l of claim 1) would have been obvious in view of the method of proving a oligonucleotide library, providing nuclear protein extracts, contacting the oligonucleotides with the nuclear protein extract, isolating separated complexed oligonucleotides, ligation of the oligonucleotide to a promoter of an expression cassette. In addition, the specific method of making would not impart characteristics on the claimed product that would patentably distinguish the product.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-19 of U. S. Patent No. 6,140,080. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species claims of patent 6,140,080 renders the

genus claims of the instant application obvious. The claimed promoter made by the method of providing a mix of oligonucleotides, contacting with nuclear proteins, isolating complexes and then the complexed oligonucleotide, amplifying the oligonucleotide by PCR, isolating oligonucleotides re electrophoretic mobility, putting the oligonucleotide with a promoter and assaying expression (steps a-l of claim 1) would have been obvious in view of the method of proving a oligonucleotide library, providing nuclear protein extracts, contacting the oligonucleotides with the nuclear protein extract, isolating separated complexed oligonucleotides, ligation of the oligonucleotide to a promoter of an expression cassette (Examples 1 & 2, columns 12-13, US 6,140,080). In addition, the specific method of making would not impart characteristics on the claimed product that would patentably distinguish the product.

Remarks

15. No claim is allowed.

16. SEQ ID NO: 2 is free of the prior art, however a 16-mer comprising a 7-mer identical to SEQ ID NO: 2 is known in the art. See Havelund, et al, US 5, 750,497, issued 12 May 1998.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for

the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia L. Helmer PhD
Patent Examiner
Art Unit 1638
March 10, 2003

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600